

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Roberts, *et al.*

(Cont. of Appl. No.: 09/631,116)

Filed: herewith

Appl. No.: to be assigned

For: **Novel Compounds with Analgesic Effect**

Art Unit: to be assigned
(1624 in parent case)

Examiner: to be assigned
(E. Bernhardt in parent case)

Atty. Dkt.: 7567/80871

Information Disclosure Statement

Commissioner of Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, **MS Patent Application**
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the listed documents are also enclosed.

Applicants also wish to make the Examiner aware of co-pending applications 10/240,037, filed on September 27, 2002; 10/149,911, filed on October 21, 2002; and 10/149,981, filed on October 21, 2002.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned attorney submits the following concise explanation of the relevance of the non-English language documents cited on the accompanying form:

Reference B15, French patent document FR 2 696 744, describes 1-(2,2-dimethylpropyl)-2-pyrrolidone derivatives useful, *inter alia*, as serotonin 5HT-2 antagonists. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C18.

Reference B16, German patent document DE 24 31 178, describes substituted cinnamoyl-piperazine-pyridyl compounds that have analgesic properties. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C19. Also, a corresponding U.S. patent (3,940,386) is cited as document A1.

Reference B17, German patent document DE 29 00 810, describes antidepressant N-benzhydryl-N'-hydroxyl-benzyl-piperazine derivatives. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C20.

Reference B18, Japanese patent document JP 7-138230, describes piperazine derivatives that act as allergy inhibitors. English abstracts corresponding to this document are cited on the accompanying list of references as documents C21, C22 and C23.

Reference C16, abstract of Hungarian patent reference HU 217619 describes piperazinecarboxamides containing phenoxyalkyl or thiophenoxyalkyl side chains. The reference also describes pharmaceutical compositions containing these compounds as active ingredients and processes by which they may be produced. A corresponding English language PCT application is included herewith and is cited on the accompanying list of references as document B1.

Reference C17, abstract of Hungarian patent reference HU 215847 describes a process for producing L-(-)-phenyl-piperazineacetamide derivatives. The reference also describes pharmaceutical compositions containing these derivatives that can be used for preventing or

limiting reperfusion damage. A corresponding English language PCT application is included herewith and is cited on the accompanying list of references as document B2.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

Applicants do not believe any fees are due for the submission of this Information Disclosure Statement other than those which have been provided. However, the Commissioner is hereby authorized to charge any fee deficiency to our Deposit Account No. 06-1135 under Order No. 7567/80871.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>				Atty. Docket No.: 7567/80871		Appl. No.: to be assigned			
				Applicant(s) Roberts, <i>et al.</i>					
				Filing Date: herewith				Group: to be assigned	
U.S. PATENT DOCUMENTS									
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate		
	A 1	3,940,386	Feb. 24, 1976	Szabo, <i>et al.</i>	260	240	Jun. 21, 1974		
	A 2	5,574,159	Nov. 12, 1996	Chang, <i>et al.</i>	544	396	Apr. 28, 1995		
	A 3	5,681,830	Oct. 28, 1997	Chang, <i>et al.</i>	514	85	Aug. 3, 1994		
	A 4	5,807,858	Sep. 15, 1998	Chang, <i>et al.</i>	514	255	Jun. 5, 1996		
	A 5	6,130,222	Oct. 10, 2000	Roberts, <i>et al.</i>	514	255.04	Apr. 24, 1997		
	A 6								
	A 7								
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FOREIGN PATENT DOCUMENTS									
Examiner Initial		Document Number	Date	Country	Class	Subclass	Abst./Trans.		
							Yes	No	
	B 1	WO 86/04584	14 August 1986	WIPO	C07D	295/14			
	B 2	WO 91/07967	13 June 1991	WIPO	A61K	31/495			
	B 3	WO 93/15062	5 August 1993	WIPO	C07D	241/04			
	B 4	WO 95/04051	9 February 1995	WIPO	C07D	295/155			
	B 5	WO 97/23466	3 July 1997	WIPO	C07D	241/04			
	B 6	WO 98/28270	2 July 1998	WIPO	C07D	211/56			
	B 7	WO 98/28275	2 July 1998	WIPO	C07D	211/70			
	B 8	WO 99/33806	8 July 1999	WIPO	C07D	211/58			
	B 9	EP 0 289 227	2 November 1988	EPO	C07D	233/64			
	B 10	EP 0 283 310	21 September 1988	EPO	C07D	295/04			
	B 11	EP 0 166 302	2 January 1986	EPO	C07D	243/08			
	B 12	EP 0 133 323	20 February 1985	EPO	C07D	295/04			
	B 13	GB 2 210 366	7 June 1989	Great Britain	C07D	295/04			
	B 14	GB 2 076 403	2 December 1981	Great Britain	C07D	241/04			
	B 15	FR 2 696 744	12 October 1992	France	C07D	401/06	X		
	B 16	DE 24 31 178	16 January 1975	Germany	C07D	295/04	X		
	B 17	DE 29 00 810	24 July 1980	Germany	C07D	295/04	X		
	B 18	JP 7-138230	30 May 1995	Japan	C07D	213/38	X		
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Examiner Initial			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)			
	C 1	Bilsky, <i>et al.</i> , "Characterization of Enantiomers of (±)BW373U86 and Related Compounds: Highly Selective Non-Peptide Delta Opioid Agonists," <i>Reg. Peptides</i> 54:25-26 (1994).	
	C 2	Bilsky, <i>et al.</i> , "SNC 80, A Selective, Nonpeptidic and Systemically Active Opioid Delta Agonist," <i>J. Pharmacol. Exper. Therap.</i> 273:359-366 (1995).	
	C 3	Burkey, <i>et al.</i> , "The Efficacy of Delta-Opioid Receptor-Selective Drugs," Medline Abstract for <i>Life Sci.</i> 62:1531-1536 (1998).	
	C 4	Calderon, <i>et al.</i> , "Probes for Narcotic Receptor Mediated Phenomena. 19. Synthesis of (+)-4-[(α R)- α -(2S,5R)-4-Allyl-2,5-Dimethyl-1-Piperazinyl]-3-Methoxybenzyl]-N,N-Diethylbenzamide (SNC 80): A Highly Selective, Nonpeptide δ Opioid Receptor Agonist," <i>J. Med. Chem.</i> 37:2125-2128 (1994).	
	C 5	Calderon, <i>et al.</i> , "Probes for Narcotic Receptor Mediated Phenomena. 23. Synthesis, Opioid Receptor Binding, and Bioassay of the Highly Selective δ Agonist (+)-4-[(α R)- α -(2S,5R)-4-Allyl-2,5-Dimethyl-1-Piperazinyl]-3-Methoxybenzyl]-N,N-Diethylbenzamide (SNC 80) and Related Novel Nonpeptide δ Opioid Receptor Ligands," <i>J. Med. Chem.</i> 40:695-704 (1997).	
	C 6	Chang, <i>et al.</i> , "A Novel, Potent and Selective Nonpeptidic Delta Opioid Receptor Agonist BW373U86," <i>J. Pharmacol. Exper. Therap.</i> 267:852-857 (1993).	
	C 7	Greene, "Protective Groups in Organic Synthesis," pp. 267-268 and 331 (1981).	
	C 8	Katritzky, <i>et al.</i> , "Benzotriazole-Mediated Arylalkylation and Heteroarylalkylation," <i>Chem. Soc. Rev.</i> 23:363-442 (1994).	
	C 9	Kingsbury, <i>et al.</i> , "Synthesis of Structural Analogs of Leukotriene B ₄ and Their Receptor Binding Activity," <i>J. Med. Chem.</i> 36:3308-3320 (1993).	
	C 10	Lopez, <i>et al.</i> , "Exploring the Structure-Activity Relationships of [1-(4- <i>tert</i> -Butyl-3'-Hydroxy)Benzhydryl-4-Benzylpiperazine] (SL-3111), a High-Affinity and Selective δ -Opioid Receptor Nonpeptide Agonist Ligand," <i>J. Med. Chem.</i> 42:5359-5368 (1999).	
	C 11	Nagase, <i>et al.</i> , "The Pharmacological Profile of Delta Opioid Receptor Ligands, (+) and (-) TAN-67 on Pain Modulation," Medline Abstract for <i>Life Sci.</i> 68:2227-2231 (2001).	
	C 12	Plobbeck, <i>et al.</i> , "New Diarylmethylpiperazines as Potent and Selective Nonpeptidic δ Opioid Receptor Agonists with Increased <i>In Vitro</i> Metabolic Stability," <i>J. Med. Chem.</i> 43:3878-3894 (2000).	
	C 13	Suggs, <i>et al.</i> , "Facile Synthesis of 8-Substituted Quinolines," <i>J. Org. Chem.</i> 45:1514-1515 (1980).	
	C 14	Takemori, <i>et al.</i> , "Selective Naltrexone-Derived Opioid Receptor Antagonists," <i>Annu. Rev. Pharmacol. Toxicol.</i> 32:239-269 (1992).	
	C 15	Zhang, <i>et al.</i> , "Probes for Narcotic Receptor Mediated Phenomena. 26. Synthesis and Biological Evaluation of Diarylmethylpiperazines and Diarylmethylpiperidines as Novel, Nonpeptidic δ Opioid Receptor Ligands," <i>J. Med. Chem.</i> 42:5455-5463 (1999).	
	C 16	Abstract for HU 217619; a corresponding English language PCT application is cited above as reference B1.	
	C 17	Abstract for HU 215487; a corresponding English language PCT application is cited above as reference B2.	
	C 18	English language abstract for FR 2 696 744, Reference B15 above.	
Examiner		Date Considered	

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<div>Examiner Initial</div> <div>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</div>			
	C 19	English language abstract for DE 24 31 178, Reference B16 above.	
	C 20	English language abstract for DE 29 00 810, Reference B17 above.	
	C 21	English language abstract for JP 7-138230, Reference B18 above.	
	C 22	English language abstract for JP 7-138230, Reference B18 above.	
	C 23	Abstract No. 8843b for JP 7-138230, Reference B18 above, <i>Chemical Abstracts</i> 124:938 (1996).	
	C 24		
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